APR 17 2009

APPENDIX 2

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

I. General Information

Applicant:	Iskra Medical d.o.o. Stegne 23, 1000 Ljubljana, Slovenia
Contact Person:	Mojca Valjavec
Phone:	+ 386 1 51 31 506
Fax:	+ 386 1 51 31 510
Preparation Date:	11-28-08

II. Device

Device Trade Name:	Iskra Medical Green IRF Prestige
Common Name:	Electrosurgical Unit and Accessories
Classification Name:	Device, Electrosurgical Cutting and Coagulation and Accessories (21 CFR 878.4400)

III. Legally Marketed Predicate Devices

- Alma Laser Accent RF System (K070004, K072699)
- Thermage ThermaCool TC system (K033942, K040135, K053365)
- Lumenis Aluma Skin Renewal system (K051214)

IV. Device Description

The Iskra Medical Green IRF Prestige system consists of a user interface, internal electronics controlled by microprocessor, RF generator, 2 treatment handpieces (small and large applicator), and reference electrode. The treatment parameters are selected and controlled via the touch screen.

V. Intended Use

The Iskra Medical Green IRF Prestige and Accessories are intended for use in dermatologic and general surgical procedures for non-invasive treatment of facial wrinkles and rhytids.

VI. Rationale for Substantial Equivalence

The Iskra Medical Green IRF Prestige system shares the same indications for use, similar design and functional features with predicate devices, and thus it has been found to be substantially equivalent to the predicate devices.

VII. Summary

As the Iskra Medical Green IRF Prestige system is substantially equivalent with respect to indication for use, materials, method of operation and physical construction to the predicate devices, we believe it clearly meets the requirements for substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Iskra Medical, d.o.o.
% Ms. Mojca Valjavec
Marketing & Sales Manager
Stegne 23, SI-1000 Ljubljana
SLOVENIA

APR 1 7 2009

Re: K083590
Trade/Device Name: ISKRA MEDICAL GREEN IRF PRESTIGE AND ACCESSORIES
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: March 18, 2009
Received: March 23, 2009

Dear Ms. Valjavec:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at (240) 276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

APPENDIX 1

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K 083590

Device Name: **ISKRA MEDICAL GREEN IRF PRESTIGE AND ACCESSORIES**

Indications for Use:

Iskra Medical Green IRF Prestige and Accessories are intended for use in dermatologic and general surgical procedures for non-invasive treatment of facial wrinkles and rhytids.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K083590